REMARKS/ARGUMENTS

In the Office Action certain claims were allowed or were indicated to be allowable but were objected to as being dependent upon a rejected base claim. The remaining claims were rejected under 35 USC §§102 and 103. Each of the objections and rejections will be responded to below.

a. Allowed claims and allowable subject matter

Claims 18-23 were allowed.

Claims 7, 9, 13, 15 and 17 were objected to as being dependent upon a rejected base claim, but were stated to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Accordingly, Applicant has added new claims 24-44. New claim 24-6 corresponds to dependent claim 7 rewritten in independent form including all of the limitations of the base claim and intervening claims, with claims 25-26 being dependent therefrom. Claim 27 corresponds to original claim 9 rewritten in independent form, including all the limitations of the base claim and intervening claims, with claims 28-32 being dependent therefrom. New claim 33 corresponds to original claim 13 rewritten in independent form, including all of the limitations of the base claim and intervening claims, with claims 34-37 being dependent therefrom. New claim 38 corresponds to original claim 17 rewritten in independent form including all of the limitations of the base claim and intervening claims, with new claims 39-42 being dependent therefrom.

Accordingly, it is believed that new claims 24-42 are in condition for allowance.

b. Response to objections under 37 CFR1.75(c)

Claim 3 was objected to under 37 CFR1.75(c), as being of improper dependent form for failing to further limit the subject matter of the previous claim. Specifically, the Examiner stated that claim 3 did not appear to further limit claim 1, in that the injection step seemed to be outside the confines of requiring a mobilizing agent in an amount sufficient to enable the liquid antibiotic to penetrate into the subdermal soft tissue.

Applicant respectfully requests that the objection be reconsidered. The term "penetration", both as it is commonly understood and as it is defined and used in Applicant's specification and claims, means the permeation and diffusion of a compound (the macrolide antibiotic) into the soft tissues. By contrast, the term "injection" refers to forcing the material into a location in the body by means of a syringe or other instrument.

When applied topically, as recited in claim 2, the macrolide antibiotic (by virtue of the mobilizing agent) passes through the skin and penetrates -- i.e., permeates and diffuses -- into the underlying soft tissue. When applied by injection (e.g., using a hypodermic needle), as recited in claim 3, the macrolide antibiotic (again by virtue of a mobilizing agent) permeates and diffuses into the soft tissue surrounding the injection site.

The "injection" cited in claim 3 (meaning injection with a syringe) is thus different from the "penetration" recited in claim 1, and claim 3 therefore further limits claim 1 in accordance with 37 CFR1.75(c). Should the Examiner deem it appropriate, however, Applicant is prepared to substitute the synonymous term "permeate" for "penetrate" in order to clarify the distinction between what is meant thereby and the term "injection" in claim 3.

c. Response to rejection of method claims 1-2, 5-6 and 8 under 35USC §102

Method claims 1-2, 5-6 and 8 were rejected under 35USC §102(b) as being anticipated by Chemical Abstracts 100:73895. Applicant respectfully traverses the rejection.

Chemical Abstracts 100:73895 discloses an antiacne ointment that contains 1% erythromycin lactobionate. The Examiner acknowledges that the reference does not spell out the steps of the method claims, but asserts that "An antiacne ointment is applied to acne. Acne is a subdermal soft tissue microbial infection. Therefore, the disclosure of an antiacne ointment necessarily discloses topically applying to the skin over subdermal soft tissue, wherein the required ointment penetrates the subdermal soft tissue to reach the microbial infection."

Applicant respectfully disagrees. The Examiner has provided no support for the assertion that "acne is a subdermal soft tissue microbial infection." Although Applicant is not an expert on acne, it is generally recognized that acne is not a subdermal microbial infection *per se*. Rather, the bacteria (which occur on the skin naturally) grow in the sebaceous secretions (oil) on the surface of the skin and in the pores around the hair follicles. These areas are outside the living tissue of the body and are accessible to fluid simply flowing over the exterior of the dermal layer.

Consequently, as it is normally understood, acne is not a soft tissue bacterial infection. Moreover, contrary to the Examiner's assertion, treatment of acne with an ointment does not inherently involve penetration of the subdermal soft tissues: an antimicrobial compound can reach the bacteria simply by flowing over the surface of the skin and into the pores without penetrating the subdermal tissues.

With regard to the composition claims 10, 12, 14, 16 and the composition features of the method claims, the Examiner has asserted that any one of Tween 80, cetylstearyl alcohol or triethanolamine (as listed in Chemical Abstracts 100:73895) will satisfy the requirement in Applicant's claims for a mobilizing agent that enables the macrolide antibiotic to penetrate into subdermal soft tissue.

Again, Applicant respectfully disagrees. There is no evidence that nay of these compounds serve as a mobilizing agent for penetrating into the subdermal soft tissues. Tween 80 and cetylstearyl alcohol are primarily surfactants, while triethanolamine is an intermediate in the formation of surfactants, as well as an emulsifier and dispersant (e.g., see *Merck Index*). While the surface active properties of these compounds may well help the material spread over the surface of the skin and flow into the pores and around the hair follicles when treating acne, the reference provides no teaching that it would help the macrolide antibiotic penetrate through the dermal layers and into the underlying soft tissue, nor is such a conclusion to be drawn from the common knowledge in the art. Chemical Abstracts 100:73895 therefore fails to show a mobilizing agent that enables the macrolide antibiotic to penetrate into the subdermal soft tissue, as is expressly required by Applicant's claims.

In short, Chemical Abstracts 100:73895 does not expressly disclose a method in which a macrolide antibiotic penetrates into the subdermal soft tissue, nor is such a method inherent in the teachings of the reference. Applicant therefore respectfully submits that the reference fails to anticipate method claims 1-2, 5-6 and 8 and requests that the rejection of the claims under 35USC §102(b) be reconsidered and withdrawn.

d. Response to §103 rejections

Claims 1 and 3 were rejected under 35USC §103(a) as being unpatentable over Macy et al. (U.S. 5,723,447). Applicant again respectfully traverses the rejection.

Examiner notes that "the reference does not explicitly state that there be a "mobilizing agent" to enable macrolide to penetrate into said sub-dermal soft tissue." Additionally, the

reference does not specifically state that the injectable formulation is for alleviating disease state resulting from microbial infection of subdermal soft tissue."

However, Examiner asserts that "one having ordinary skill in the art would have been motivated to use the known subcutaneous administration of the antibiotic erythromycin for the purposes of controlling microbial infections near the locus of administration, i.e., subcutaneous/subdermal and other microbial infections. As for the "mobilizing agent," the vehicles disclosed by the reference [propylene glycol monomethyl ether, dipropylene glycol monomethyl ether, diethylene glycol ethyl ether, or N-methyl pyrrolidone] qualify as such because of their solvating and surface acting properties."

Applicant respectfully disagrees. Not only does Macy et al. not explicitly state that the vehicles are for enabling the macrolide to penetrate into the subdermal soft tissue, the reference in fact teaches against it. Macy et al. is expressly directed to a water-miscible solution of erythromycin, for the purpose of improved intravenous administration that will rapidly provide therapeutic blood levels. (Col. 1, lines 40-44). Consequently, the reference states that a principle object of the water-miscible solution is that it will allow for more rapid absorption from intramuscular and subcutaneous injection sites, leading to a higher concentration in the body fluids (e.g., the blood stream), as opposed to penetrating into and permeating the soft tissues as in the present invention (see col. 1, lines 35-48). In short, the purpose of Macy's water-miscible solution is to be quickly withdrawn from the tissues so that it will enter the bloodstream, which is the opposite of penetrating into and permeating the soft tissues as required by Applicant's claims. This is confirmed by the nature of the target diseases that are listed by Macy et al.: pneumonias, mastitis, metritis, rhinitis, and bronchitis. All of these conditions concern organs that are heavily involved with the circulatory and/or respiratory systems and that are ordinarily treated by intravenous (or sometimes oral) administration.

As a result, Macy et al. would not suggest use of the compositions for penetrating into subdermal soft tissue, since this would delay absorption of the erythromycin into the bloodstream and therefore defeat the express purpose of the invention. Conversely, since the purpose of Macy et al. is to ensure rapid withdrawal of the erythromycin from the tissues so that it will quickly enter the bloodstream, one having ordinary skill in the art would not have been motivated to use the preparations for the purpose of controlling microbial infections near the locus of administration, since Macy teaches that the "stay time" of the erythromycin near the injection site will be very short.

Finally, as for the specific compounds that are listed by Macy and have been identified by the Examiner as constituting "mobilizing agents" (the various ethers and methylpyrolidol), these have solvent characteristics that may well help form the stable, water-miscible formulations of erythromycin to which Macy et al. is directed, but there is no evidence to support the Examiner's contention that these compounds would enable a macrolide antibiotic to penetrate/permeate into subdermal soft tissues.

Accordingly, Applicant respectfully submits that (a) Macy et al. fails to expressly teach the method of Applicant's claims 1 and 3, and (b) one skilled in the art would not be motivated to modify Macy et al to use the compositions thereof in Applicant's claimed method, since the reference itself teaches against such a use. Applicant therefore respectfully requests that the rejection of claims 1 and 3 under 35USC §103 be reconsidered and withdrawn.

e. Conclusion

Applicant respectfully requests reconsideration of the present application in view of the amendments and remarks set forth herein. It is believed that the above-referenced claims are now in condition for allowance. If there is any matter that can be expedited by consultation with Applicant's attorney, such would be welcome. Applicant's attorney can normally be reached at the telephone number given below.

Signed at Bellingham, County of Whatcom, State of Washington this 17th day of November 2003.

Respectfully submitted,

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